January 29, 2016

Mr. David Seltz
Executive Director
Massachusetts Health Policy Commission
50 Milk Street
Boston, MA 02109

Dear Mr. Seltz,

On behalf of the Massachusetts Medical Device Industry Council (MassMEDIC) and the Advanced Medical Technology Association (AdvaMed), we are pleased to submit these written comments on the Health Policy Commission's Proposed Accountable Care Organization (ACO) Certification Standards.

We are both available to meet with you at a convenient time to discuss our recommendations with you and your colleagues.

Thank you very much for this opporutnity and for considering our position.

Sincerley,

Thomas J. Sommer
President
MassMEDIC

David Nexon
Senior Executive Vice President
AdvaMed

COMMENTS TO THE HEALTH POLICY COMMISSION ON DRAFT ACO CERTIFICATION REQUIREMENTS
January 2016

On behalf of the Massachusetts Medical Device Industry Council (MassMEDIC) and the Advanced Medical Technology Association (AdvaMed), we respectfully request the Commission to support the value and benefits offered by medical technology in advancing the health and well-being of patients in Massachusetts and in furthering the goals of health reform. As ACOs and other provider arrangements aim to reduce costs and drive efficiencies, it is critical that these arrangements support early access to important new screening, diagnostic and treatment technologies. These technologies are essential to improving the quality of care, reducing long term system costs and screening, diagnosing and treating diseases, key goals articulated in the introduction to the commission's draft guidelines and in the underlying legislation.

Nationally, medical devices and diagnostics have been key contributors to greater longevity and improved quality of life and to cost reduction. Between 1980 and 2013, medical advances helped add over five years to U.S. life expectancy, while cutting fatalities from heart disease and stroke by more than half.[1] The pace of improvement has accelerated in recent years. On the cost front, medical technologies have been important factors in cutting per capita hospitals days by almost 60 percent between 1980 and 2010.[2] Minimally invasive surgeries reduce health spending $8.9 billion annually.[3] Insulin pumps reduce annual costs for treating diabetics by $600 per person.[4] New diagnostic testing methodologies that can more rapidly detect serious infections like sepsis can lower hospital costs for treating these infections by 30 percent.[5] In a chronically ill population, the use of telehealth services to aid in patient management has reduced per patient costs by almost $900 per patient per year.[6] New technologies can also save costs relative to existing therapies. For example, left atrial appendage closure was found to be less costly over time when compared to novel oral anti-coagulants and warfarin in reducing the risk of stroke for patients with non-valvular atrial fibrillation.[7] The impact of technology on social and governmental costs outside the health care system has been even greater. A conservative estimate of the total financial impact of selected technologies in treating and diagnosing diabetes, heart disease, osteoarthritis, and colon cancer found a net economic benefit of $24 billion annually, taking into account increases in labor force participation and productivity arising from treatment.[8]

With its vibrant medical technology industry and its concentration of academic health centers and medical researchers, Massachusetts is a national leader in creating new screening, diagnostic and treatment technologies that are essential ingredients in improving patient care and population health and reducing long-term costs. Not only does the statute set a general goal of improving the quality of care, the health reform law specifically authorizes the Commission to consider ways of "ensuring patient access to health care services across the care continuum, including breakthrough technologies and treatments."

Although improved quality and cost control are central goals of the ACO program, the lack of specific policies to support adoption of new, clinically important technologies in the current draft may be counterproductive to

achieving both goals. Some important clinical advances increase costs, but the purpose of the ACO program is to reduce overall costs while improving quality—not to deny patients access to the fruits of medical progress or to inhibit development of future treatment breakthroughs in the name of "cost savings". Larger opportunities exist for saving through better organization of the care delivery process, reduced medical errors, improved programs to prevent disease, and improved outcomes that reduce the burden of disease. These savings can be achieved without denying Massachusetts patients access to the care they need.

In addition, it is not uncommon for truly breakthrough technologies to increase the short-term cost of care but reduce long-term costs. The incentive systems built into most of the new payment mechanisms—including ACOs--penalize providers for short-term cost increases but fail to reward them for long-term cost savings or for long-term value added to society. Thus, a correction is essential.

The Medicare program has recognized this in its new bundled payment program—which has a similar incentive structure to an ACO-- by adjusting the incentive structure so that participants in the program are not penalized for adoption of clinically important new technologies recognized by Medicare's new technology add-on payment program for inpatient services.

In conclusion, MassMedic and AdvaMed commend the Commission for its work to date and recommend that the Commission uses its authority to add an additional domain to the current list of ACO qualification standards that would address the need to support adoption of clinically important new technologies, including screening, diagnostic, therapeutic and telehealth services. We stand ready to work with the Commission to develop the best possible ways to approach this issue and are hopeful that if the Commission is not able to add such a domain in this year's final ACO certification requirements, it would indicate its recognition of the importance of this issue and its intention to work on its resolution for future updates of the requirements.

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[1] National Center for Health Statistics. "Health, United States, 2014: With Special Feature on Adults Aged 55-64." Hyattsville, MD. May 2015.

[2] National Center for Health Statistics. (2013, March 14). Table 103 – Discharges, days of care, and average length of stay in nonfederal short-stay hospitals, by selected characteristics: United States, selected years 1980 through 2009-2010. Retrieved March 15, 2013, from Centers for Disease Control and Prevention: http://www.cdc.gov/nchs/data/hus/2011/103.pdf.

[3] A. Epstein, P. Groeneveld, M. Harhay, et al., "Impact of Minimally Invasive Surgery on Medical Spending and Employee Absenteeism," Journal of the American Medical Association Surgery magazine, published online March 20, 2013, www.jamasurg.com.

[44] Anusuya Chatterjee et al., "Health Savings: Medical Technology and the Economic Burden of Disease," Milken Institute, July 2014.

[5] "Rapid Diagnosis of Infections in the Critically Ill (RADICAL) study" of Abbott's *Iridica* platform, 2014, Abbott.

[6] Data from a program conducted by Banner Health.

[7] Reddy VY, Akehurst RL, Armstrong SO, Amorosi SL, Beard SM, Holmes DR, Jr.. Time to Cost-Effectiveness Following Stroke Reduction Strategies in AF: Warfarin Versus NOACs Versus LAA Closure. *J Am Coll Cardiol.* 2015;66(24):2728-2739. doi:10.1016/j.jacc.2015.09.084.

[8] Chatterjee et al., op. cit.

MassMEDIC & AdvaMed Comments on
Proposed Accountable Care Organization (ACO) Certification Standards
Health Policy Commission
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Appendix A

II. Proposed HPC ACO Certification Framework

A. Approach

- Market and patient protections: ACOs seeking certification by the HPC must attest to being in compliance with all legal and regulatory requirements related to market and patient protection.

  MassMEDIC suggests that ACOs seeking certification must *demonstrate* that it is in compliance with all legal and regulatory requirements related to market and patient protection.

B. Criteria and Documentation Requirements

- Table 1 lists HPC proposed criteria and associated documentation requirements. Please note that the documentation requirements for ACO applicants may include submission of nonpublic, clinical, financial, strategic or operational documents and information. The HPC shall not disclose such information and documents without the consent of the ACO applicant submitting the required information and documents, except in summary form in evaluative reports or when the HPC believes that such disclosure should be made in the public interest after taking into account any privacy, trade secret or anticompetitive considerations. The confidential information and documents received from ACO applicants shall not be public records and shall be exempt from disclosure under clause Twenty sixth of section 7 of chapter 4 or section 10 of chapter 66.

  MassMEDIC and AdvaMed recommend that the HPC clearly identify those areas that would be non-public and require all other information to be made public.

D. **Questions for Public Comment**

- The HPC seeks input on the proposed certification framework, individual criteria, and documentation requirements. In particular, Table 1 lists criteria-specific questions, on which the HPC is especially interested in receiving public comment.

  MassMEDIC and AdvaMed recommend that the HPC clearly define under what circumstances an ACO could be decertified as well as the process t for decertification.

- Do you favor the HPC making public the application materials submitted for ACO certification?

  MassMEDIC and AdvaMed favor making these application materials available to the public with the exception of non-public information discussed in the previous criteria.

Table 1: Proposed HPC ACO certification criteria, documentation requirements, and questions for public comment

#2 - The ACO provides information about its participating providers to HPC, by Tax Identification Number (TIN), for each of the three payer categories (Medicare, MassHealth, commercial).*

Narrative of why an ACO's participating providers may differ by Medicaid, Medicare or commercial contracts.

MassMEDIC and AdvaMed assume that this information will not be confidential.

#3 - The ACO governance structure includes a patient or consumer representative. The ACO has a process for ensuring patient representative(s) can meaningfully participate in the ACO governance structure.

Describe and give examples of meaningful participation. What evidence should the HPC seek to assess meaningful participation?

MassMEDIC and AdvaMed suggest that a *patient* representative be appointed to the ACO's governing board.

#6 - The ACO has a quality committee reporting directly to the ACO board, which regularly reviews and sets goals to improve on clinical quality/health outcomes (including behavioral health), patient/family experience measures, and disparities for different types of providers within the entity (PCPs, specialists, hospitals, post-acute care, etc.).

MassMEDIC and AdvaMed suggest that the HPC also consider requiring the ACO's quality committee to have input on patient and consumer complaints.

#8 - Using data from health assessments and risk stratification or other patient information, the ACO implements one or more programs targeted at improving health outcomes for its patient population. At least one of these programs addresses mental health, addiction, and/or social determinants of health.

Should the HPC be more prescriptive with this requirement (i.e., require more than one program)?

MassMEDIC and AdvaMed believe that the HPC should be more prescriptive, requiring outcomes-based results, not just the metric that are used to measure performance.

#9 – ACO demonstrates and assesses effectiveness of ongoing collaborations with and referrals to:
- Hospitals
- Specialists
- Post-acute care providers (i.e., SNFs, LTACs Etc.)

What evidence should the HPC seek to evaluate whether ACOs assess the effectiveness of the collaborations?

MassMEDIC and AdvaMed recommend that the HPC should require submission of actual results, including referral patterns, changes in use and cost across partners, etc. in order to assess the effectiveness of such collaboration. Further, the HPC could establish thresholds to ensure continued progress in fostering such collaboration.

#11 - The ACO participates in a **budget-based contract for Medicaid patients by the end of Certification Year 2 (2017)**.*

Would a relative threshold be more meaningful? That is, measure ACOs' increase in rates of budget-based contracts year over year? Should a relative threshold be different for larger and smaller ACOs?

No. The HPS could require that an ACO must participate in a budget-based contract for Medicaid, however we recommend that MassHealth be responsible for negotiating the contract as well as performance measures with each ACO. These certification requirements should address the basic capabilities and infrastructure of ACOs . Each payer should have the flexibility to determine financial contracts, including financial performance measures, with each ACO rather than have such measures set by the HPC.

#30 -The ACO **distributes funds** among participating providers using a methodology and process that are **transparent** to all participating providers. Documentation must include both a description of the methodology and a demonstration of communication to all participating providers.

MassMEDIC and AdvaMed recommend that the methodology and process should be transparent to the public and patients, as well as providers. In view of the potential for reimbursement methodologies to impact provider behavior, patients, the public and researchers should be able to assess independently whether the right balance has been struck between incentives to reduce costs, maintain quality and satisfy patient expectations.